DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

SEP 16

Andrx Pharmaceuticals, Inc.
Attention: Diane Servello
4001 S.W. 47th Ave.
Ft. Lauderdale, FL 333 14

Docket No. 98P-0225/CP I

Dear Ms. Servello:

This is to inform you of new regulations that will affect any Abbreviated New Drug Application (ANDA) you file on or after April 1, 1999 that relies on a suitability petition approved by the Agency before April 1, 1999. Specifically, on December 3, 1998, the Agency approved your petition filed on April 9, 1998, and amended April 29, 1998, requesting permission to file an ANDA for the following drug products: Omeprazole Delayed-release Tablets, 10 mg and 20 mg. The listed drug products to which you refer in your petition are Prilosec® (Omeprazole) Delayed-release Capsules, 10 mg and 20 mg manufactured by Astra Merck, Inc.

Your request involved a change in dosage form from that of the listed drug products (i.e., from delayed-release capsule to delayed-release tablet). The change you requested is the type of change that is authorized under the Act.

This petition was originally approved pursuant to Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (Act). Under Section 505(j)(2)(C)(i) of the Act, a petition requesting a change in dosage form will be approved unless the Agency finds that investigations must be conducted to show the safety and effectiveness of the differing dosage form.

However, you did not file an ANDA based on your approved suitability petition before April 1, 1999, the effective date of the Regulations Requiring Manufacturers to Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients; Final Rule, published , December 2, 1998, in the Federal Register (Pediatric Rule)(63 FR 66632). Therefore, the agency has reevaluated your petition with respect to the Pediatric Rule.The agency has determined that your proposed change in dosage form is subject to the Pediatric Rule and has concluded that investigations are necessary to demonstrate the safety and effectiveness of Omeprazole Delayed-release Tablets, 10 mg and 20 mg in the pediatric population (see Preamble to Pediatric Rule 63 FR 66640-41). Therefore, FDA is withdrawing the December 3, 1998, approval of your petition under 21 CFR 314.93(f) and is denying the petition under Section 505(j)(2)(C)(i) because investigations are necessary to show the safety and effectiveness of the proposed drug products. We suggest that you contact the Division of Gastrointestinal and Coagulation Drug Products at (301) 827-73 10 for further information.

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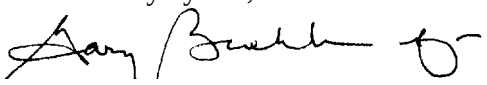
If you disagree with our determination concerning the acceptability of your petition as originally submitted, you may seek a reconsideration of the denial following the procedures set forth in 21 CFR 10.33. Requests for reconsideration must be based solely on the information contained in your original petition and must be submitted in accordance with 21 CFR Section 10.20, in the format outlined in Section 10.33 and no later than 30 days after the date of the decision involved. Petitions for reconsideration should be filed with the Dockets Management Branch at the address listed below. If there is additional information, not included as part of your original submission that you would like the Agency to consider, you should submit a new petition including all the necessary information to the Dockets Management Branch.

A copy of this letter withdrawing approval and denying your petition will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely yours,



Douglas' L. Spom
Director
Office of Generic Drugs
Center for Drug Evaluation and Research